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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTELLAS US LLC, ASTELLAS PHARMA US, INC., and ITEM DEVELOPMENT AB, Plaintiffs, v. WOCKHARDT LIMITED and WOCKHARDT USA, INC. a/k/a WOCKHARDT USA LLC, Defendants.	Civil Action No.: **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs, Astellas US LLC, Astellas Pharma US, Inc., and Item Development AB (hereinafter collectively "Plaintiffs"), bring this action for patent infringement against Wockhardt Limited and Wockhardt USA, Inc. a/k/a Wockhardt USA LLC (hereinafter

collectively "Defendants"). This action concerns a patent relating to the use of adenosine, a prescription drug, as an adjunct to thallium-201 myocardial perfusion scintigraphy, used in the diagnosis of coronary artery disease in patients unable to exercise adequately.

JURISDICTION AND PARTIES

1. Plaintiff Astellas US LLC (hereinafter "Astellas US") is a limited liability corporation organized under the laws of Delaware having an office and principal place of business at Three Parkway North, Deerfield, IL 60015-2548.

2. Plaintiff Astellas Pharma US, Inc. (hereinafter "Astellas Pharma") is a corporation organized under the laws of Delaware having an office and principal place of business at Three Parkway North, Deerfield, IL 60015-2548.

3. Astellas US and Astellas Pharma (collectively hereinafter "Astellas") are engaged in the business of research, development, and sale of pharmaceutical products throughout the United States.

4. Plaintiff Item Development AB (hereinafter "Item"), is a Swedish corporation having an office and principal place of business at Svanholmsvagen 2A, Stocksund, SE-18275, Sweden.

5. Upon information and belief, Defendant Wockhardt Limited (hereinafter "Wockhardt Ltd") is a company organized and existing under the laws of India and maintains a principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai 400 051, Maharashtra, India. On information and belief, Wockhardt Limited, itself and through its wholly owned subsidiary and

agent, Wockhardt USA, LLC, is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

6. Upon information and belief, Defendant Wockhardt USA, Inc. a/k/a Wockhardt USA LLC (hereinafter "Wockhardt USA") is a company organized and existing under the laws of Delaware and maintains an office at 20 Waterview Blvd., Parsippany, NJ 07054. On information and belief, Wockhardt USA is a wholly owned subsidiary of Wockhardt EU Operations (Swiss) AG, which in turn is a wholly owned subsidiary of Wockhardt Ltd. On information and belief, Wockhardt USA is the wholly-owned subsidiary and agent of Wockhardt Ltd. On information and belief, Wockhardt USA, on behalf of Wockhardt Ltd., sells and markets generic pharmaceutical products for distribution in the State of New Jersey and throughout the United States.

7. The Court has personal jurisdiction over the Defendants because, on information and belief, they have maintained continuous and systematic contacts with the State of New Jersey, as they would have cause to reasonably expect to be haled into Court in New Jersey. Among other things, upon information and belief, Defendants place goods into the stream of commerce for distribution in New Jersey and throughout the United States. Upon further information and belief, Defendants have purposefully availed themselves of the benefits and protections of the laws of the State of New Jersey.

8. This action for patent infringement arises under the United States Patent Laws, Title 35, United States Code, including 35 U.S.C. §§ 271(b), (c), and (e), and §§ 281-285. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under one or more of 28 U.S.C. §§ 1391(b), (c), and (d), and § 1400(b).

BACKGROUND

9. On March 24, 1998, the United States Patent and Trademark Office duly and legally issued United States Patent No. 5,731,296 ("the '296 patent") to Item for SELECTIVE VASODILATION BY CONTINUOUS ADENOSINE INFUSION. A copy of the '296 patent is attached hereto as Exhibit A.

10. Astellas is the exclusive licensee, with right to bring suit, of certain rights in the '296 patent and, pursuant to those rights, sells Adenoscan®, an adenosine-based product approved by the United States Food and Drug Administration ("FDA") for use as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately.

11. The use of Adenoscan® in accordance with its FDA-approved labeling is covered by one or more of the claims of the '296 patent.

12. A letter dated July 31, 2009 and received at Astellas on August 3, 2009, was sent by counsel for Wockhardt Ltd. notifying Astellas that Wockhardt Ltd. had sought approval from the FDA to begin selling Adenosine Injection, USP as a generic substitute for Adenoscan® prior to the expiration of the '296 patent and alleging that the '296 patent claims were invalid or not infringed. This notice letter failed

to identify an agent in the United States who is authorized to accept service of process as required by 21 C.F.R. § 314.95(c)(7).

13. Wockhardt Ltd. has filed with the FDA an Abbreviated New Drug Application ("ANDA") No. 79-147 for "Adenosine Injection, USP, 3 mg/mL" under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of adenosine as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately.

14. Upon information and belief, Wockhardt's Adenosine Injection, USP Package Insert will have the same indications and dosage instructions as those contained in the FDA-approved Adenoscan® intravenous injection product package insert so that use of Wockhardt's Adenosine Injection, USP according to its approved labeling will result in infringement of one or more claims of the '296 patent.

15. Upon information and belief, Wockhardt Ltd. has filed an amendment to ANDA 79-147 containing a purported certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

16. Upon information and belief, Wockhardt Ltd., acting through its Wockhardt USA subsidiary, intends to engage in the commercial manufacture, use, advertising, importation, offer for sale, and/or sales of Wockhardt Ltd.'s Adenosine Injection, USP, with its associated instructions for use and labeling, promptly upon receiving FDA approval to do so.

17. Upon information and belief, Wockhardt USA has acted in concert, actively aiding, abetting, encouraging, and inducing Wockhardt Ltd. in filing ANDA No. 79-147 for "Adenosine Injection, USP, 3 mg/mL" and in preparing to sell, in the United States, a finished dosage pharmaceutical product that will contain adenosine and carry associated labeling pursuant to that ANDA.

18. Upon further information and belief, Wockhardt USA will continue to actively aid, abet, encourage, and induce Wockhardt Ltd. to sell Adenosine Injection, USP, with its associated labeling under ANDA No. 79-147, if the ANDA is approved by the FDA.

COUNT I

PATENT INFRINGEMENT

19. Under 35 U.S.C. § 271 (e)(2)(A), Wockhardt Ltd. infringed one or more claims of the '296 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '296 patent, of Adenosine Injection, USP labeled for use as an adjunct to thallium-201 myocardial perfusion scintigraphy, a product the use or sale of which would contribute to or induce the direct infringement of one or more claims of the '296 patent by ultimate purchasers.

20. Upon information and belief, Wockhardt USA has also induced or contributed to and will induce or contribute to infringement of one or more claims of the '296 patent by acting in concert and actively aiding, abetting, encouraging, and inducing Wockhardt Ltd. (1) to file ANDA No. 79-147 for " Adenosine Injection,

USP, 3 mg/mL", (2) to prepare to sell such an Adenosine Injection product pursuant to that ANDA, and (3) upon FDA approval, to sell such an Adenosine Injection product together with instructions and labeling which will result in direct infringement of one or more claims of the '296 patent by ultimate purchasers.

21. Plaintiffs will be substantially and irreparably damaged and harmed if Defendants' infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

COUNT II

DECLARATORY JUDGMENT

22. Paragraphs 1-21 are incorporated herein by reference.

23. Upon information and belief, Defendants have acted in concert and made substantial preparations to sell Adenosine Injection, USP labeled for the same indications and the same dosage and method of use as the Adenoscan® product sold by Astellas.

24. Upon further information and belief, Defendants intend to commence sales of such Adenosine Injection, USP immediately upon receiving approval from the FDA.

25. The manufacture, importation, sale, and offer for sale of Adenosine Injection, USP so labeled, once approved by the FDA, will induce and contribute to infringement of one or more claims of the '296 patent.

26. Defendants' actions in actively aiding, abetting, encouraging, and inducing sales of such Adenosine Injection, USP threaten to and will induce and/or contribute to infringement of one or more claims of the '296 patent.

27. Plaintiffs will be substantially and irreparably damaged and harmed if Defendants' threatened infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

EXCEPTIONAL CASE

28. Paragraphs 1-27 are incorporated herein by reference.

29. This is an exceptional case warranting imposition of attorney fees against Defendants under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment against Defendants as follows:

(a) finding that Defendants have infringed one or more claims of the '296 patent by filing the aforesaid ANDA relating to Wockhardt Ltd.'s Adenosine Injection, USP;

(b) prohibiting any approval by the FDA of Defendants' aforesaid Adenosine Injection, USP on any effective date prior to the date of expiration of the '296 patent;

(c) declaring that Defendants will infringe one or more claims of the '296 patent if Wockhardt Ltd.'s aforesaid ANDA relating to Adenosine Injection,

USP is approved and the approved product is sold and used in the United States;

(d) enjoining Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them or any of them, from the commercial manufacture, use, or sale of an Adenosine Injection, USP product labeled for use in myocardial perfusion imaging until the expiration of the '296 patent;

(e) finding that this is an exceptional case and granting Plaintiffs reasonable attorney fees pursuant to 35 U.S.C. § 285; and

(f) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

Respectfully submitted,

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Dated: September 10, 2009

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify pursuant to Local Civil Rule 11.2 that this matter in controversy is not the subject of any other action pending in any court, arbitration or administrative proceeding.

Dated: September 10, 2009

Joseph F. Lagrotteria
Gregory S. Thomas